PROTOCOL TITLE:

Testing Feasibility of Motivational Interviewing for Patient-Reported Cancer Pain Goals

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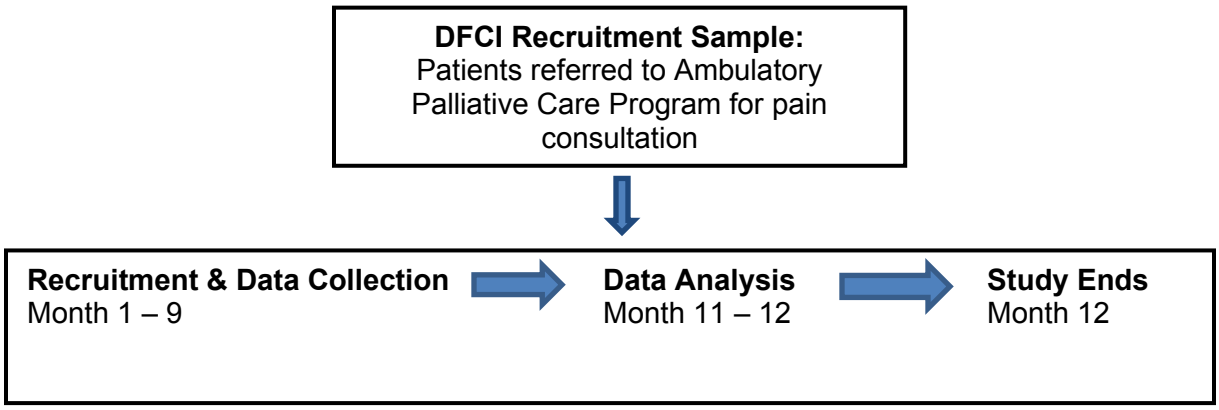
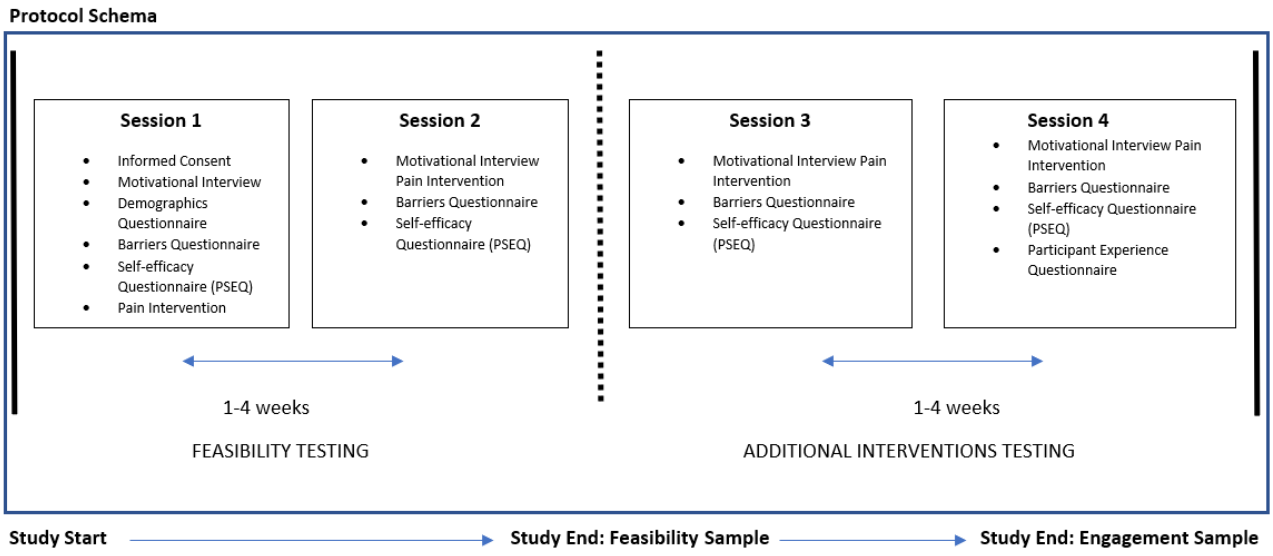
Table of Contents

1.0 Abbreviations

MI	motivational interviewing
IRB	institutional review board
PPG	personal pain goal
FPG	functional pain goal
BQII	Barriers Questionnaire II
PSEQ	Pain Self-Efficacy Questionnaire
MISHCE	Motivational Interviewing Skills in Health Care Encounters
PEQ	Patient Experience Questionnaire
OET	Observed Engagement Table

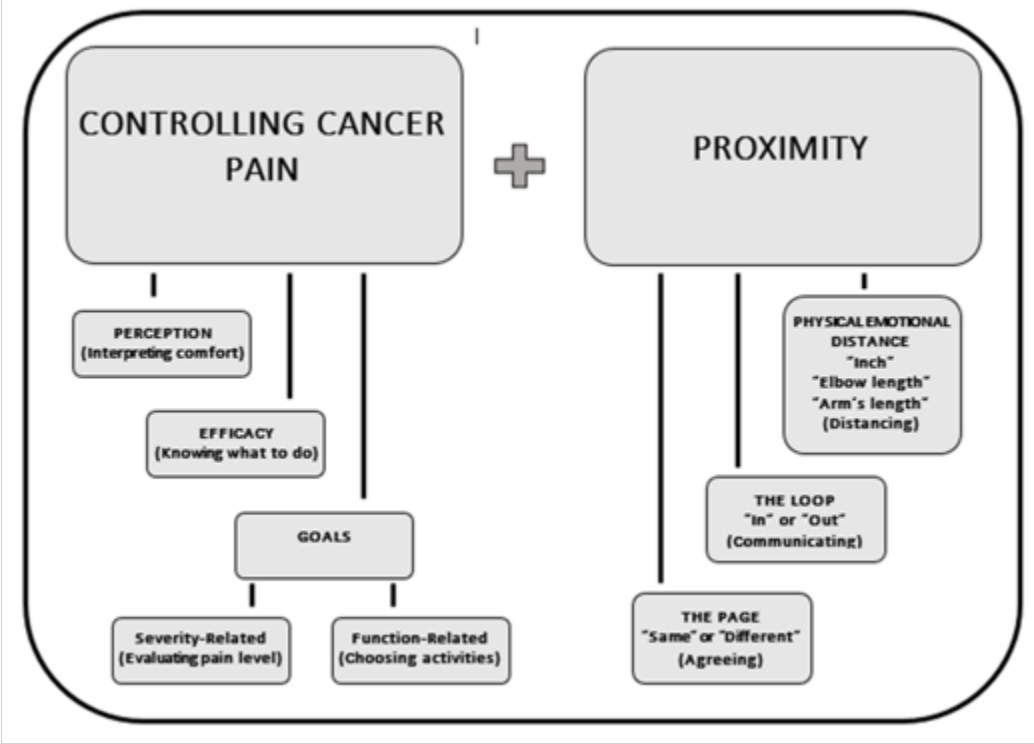
Study Schema





2.0 Figure 1-Theoretical Framework

Cancer Pain Social Processes Theoretical Framework (Ehrlich & Walker, 2018)



3.0 Objectives*

Purpose: To evaluate the acceptability and feasibility of using a cognitive behavioral intervention called motivational interviewing (MI) to help persons with pain from cancer set goals for managing their pain and improving pain control. Using MI, in our study the researcher will guide patients in goals-focused discussion of their cancer pain. At this time, there are no tested methods that clinicians can use for helping patients set these kinds of functional cancer pain goals (FPGs), despite the importance goal-setting in planning and managing healthcare behavior interventions. The study aims are:

Aim one: Evaluate the feasibility of motivational interviewing with regard to a) completion rate of a baseline and at least one follow-up study visit; b) the number of completed sessions; and c) patient acceptability of nurse-led motivational interviewing to set FPGs in the ambulatory palliative care setting.

Aim two: Explore relationships between patient-reported pain self-efficacy, attitudinal barriers to pain, and observed engagement in a motivational interviewing intervention focused on FPGs.

4.0 Background*

4.1 The Prevalence and Problem of Pain

Despite decades of research about cancer pain treatment, patients with advanced cancers have rates as high as 64% of moderate-to-severe pain (van den Beuken-van Everdingen, 2016).[1] In a 1998 seminal study, Turk et al. found that for persons with cancer pain, greater levels of anxiety were significantly correlated with lower levels of activity.[2] Although the fear of cancer pain is referenced in research papers making the case for improved pain control,[3,4,5] only one study has measured its prevalence.[6] LeMay et al. in a descriptive cross-sectional study measured fear of cancer pain prevalence and reported that patients with advanced cancers feared pain. Patient-reported fear of pain and pain severity were both significantly correlated with reduced self-reported functional capacity (B 0.19 $p<.001$, B 2.68 $p<.001$, respectively).[6] Yet, it is unknown if fear contributes to worse pain, or if having had pain generates fear of pain. Attitudinal barriers patients reported, such as fear of addiction to opioids, also have been identified and positively correlated with pain severity ratings.[7,8] An intervention which reduced patient barriers and increased patient feelings of power to control pain led to greater functional capacity.[9] In a review of 74 longitudinal cancer pain intervention studies, Sauzet et al. reported the problematic finding that a lack of statistical outcomes reporting prevented definitive conclusions between interventions and sustained effects from being made.[10] In our grounded theory study exploring social processes related to end-stage cancer pain management, when talking about times of good pain control respondents spoke of the importance of functional capacity by describing their activities.[11] We ascribed this activity talk to the social processes concept of 'goals', one of six fundamental pain management components. However, these participants who alluded to functional pain goals through indirect talk were not discussing or setting functional pain goals (FPGs) during routine pain management visits.[11] While goal-setting may seem like a logical step in a symptom management intervention, studies about goal-setting for managing pain have been limited to setting personal pain goals (PPGs), the numeric rating at which pain is considered tolerable,[12,13] and have not resulted in significant patient-reported pain reductions[13] or have not tested the effect of setting goals as an element of intervention.[14] To date, there are no clear guidelines about how or when to assess cancer pain goals, and whether establishing patient-reported functional pain goals can contribute to reduction of moderate-to-severe pain. More research is needed to understand how patients' FPGs can be assessed, discussed, and implemented in managing cancer pain.

4.2 Cancer Pain Interventions Gaps

Societal guidelines exist for cancer pain treatment, including acute, chronic, and breakthrough types,[15,16] and researchers have identified barriers at the patient, caregiver, and clinician levels. Several systematic reviews of the literature on educational interventions for cancer pain self-management have concluded that across studies,

generalizations about which types of interventions are effective cannot be made due to heterogeneity of interventions and mixed results reported within types of interventions delivered.[17,18,19] For the most recent of these reviews, in 31% of the 26 randomized control trials (RCTs) included (dating from 1995 to 2017), authors reported significant differences in pain reduction for intervention and control groups in studies using combined video or written materials with in-person coaching.[19] All but one of the included studies also measured and reported improved pain knowledge or barriers. However, because of the overall heterogeneity of interventions and outcomes measures, unclear reporting of study methods, and variations in intervention timing, the review authors were unable to make recommendations for effective cancer pain educational interventions.[19] Another under-reported outcome in the review was testing of patient self-efficacy.[19] Two cited studies reported on self-efficacy.[18,20] Kravitz et al. studied general patient self-efficacy.[20] Koller et al. used a nurse coaching intervention to increase knowledge and reduce pain intensity with significant positive changes in pain knowledge but no significant reductions in patient reported pain intensity or increases in patient pain self-efficacy.[18] In a literature review about motivational interviewing (MI), Jensen et al. reported that MI was effective for increasing self-care efficacy, and self-efficacy had been correlated with long-term pain coping, severity, and interference outcomes.[21]

Cancer pain can be acute, chronic, and breaking through at unexpected times, so early adaptive pain coping could be crucial for preventing pain crises and hospitalizations, as well as anxiety and distress over the course of the cancer illness trajectory. Vallerand et al. conducted an RCT of 317 African American patients with recent cancer pain ratings equal to or greater than 4/10, with 34% of the control group and 26% the intervention group having metastasized cancers.[9] They reported that for participants in the Power Over Pain intervention group, perceived control over pain was significantly correlated with increased function ($p=0.121$) and decreased distress ($p=-0.09$).[9] Wang et al. provided a telephone intervention to 137 patients with severe cancer pain (≥6 of 10) compared to 137 patients in a control group receiving usual care.[22] While there were significant reductions in self-reported pain severity over the 12-month study period, the reductions were associated with patients who reported lower initial pain scores, were of higher socio-economic status, lower co-morbid burden, and concurrently reported reduced levels of depression.[22] Vancleef & Peters studied relationships in 79 healthy volunteers who were randomly assigned to perceived pain control and self-efficacy groups and exposed to painful stimuli. They found significantly lower anticipated and actual pain intensity reporting in the high self-efficacy group, and nonsignificant but improved anticipated and actual pain intensity in the perceived control group.[23] Although the exact mechanisms which modulate self-efficacy and related symptoms have not been identified, interventions to increase patient self-efficacy in managing cancer pain have been studied.[23] Kelleher et al. reported that in a descriptive study of patient reported outcomes in cancer (n=178 breast and GI cancer patients), there were significant correlations between pain self-efficacy and intensity scores ($-.31$, $p<.001$) and pain self-efficacy and functioning ($-.29$, $p<.001$).[24]

4.3 The Gap in Assessing and Managing Pain Clinically Using Cancer Pain Goals

Notable gaps in clinical practice research for cancer pain management exist for the processes of assessing and setting goals. Few studies have reported on use and testing of patient pain goals. Several recent studies assessed the feasibility of clinicians asking for and documenting use of personal pain goals (PPGs), where patients are asked to report a number between zero and ten at which their pain is tolerable. Fainsinger et al. conducted a descriptive longitudinal research study of 300 patients with cancer pain to compare stabilized-pain outcomes from PPGs with those from the Edmonton Classification System for Cancer Pain (ECS-CP) definition.[12] They found no significant differences in sensitivity and specificity of the two measures, except that for persons rating their initial pain as severe, the PPG, or patient reported goal, was more sensitive for detecting stabilized-pain later in the study than the ECS-CP.[12] No research studies have implemented this recent finding that points to the potential utility of this patient-reported outcome variable, the PPG. However, Zylla et al. conducted an institution-wide quality improvement initiative to determine feasibility and practice change in clinician assessment of PPGs.[13] The investigators reviewed approximately 3,000 pain values from electronic health

records each month over the 12-month program implementation period. Although there was a 71% increase (χ^2 $p < .001$) in clinician use of PPGs in conjunction with clinician and patient educational interventions, there were no decreases in reported pain for patients with moderate-to-severe rates (data not provided).[13] Koller et al. included open-ended goal-setting in their RCT intervention study but did not test for statistical effects of this element of the intervention.[14] Because cancer patients describe good pain days as those when they can function with as much normalcy as possible,[11] and functionality is associated with reduced anxiety,[2] less fear of pain,[6] and feelings of empowerment,[9] research which explicitly solicits FPGs from patients during clinical pain management encounters is warranted. Accordingly, our study will test feasibility of using MI as a nurse-led intervention for patient-reported cancer pain goal-setting.

4.4 Theoretical Framework and Preliminary Data

This study approaches the problem of cancer pain from a social processes theoretical framework illustrated in Figure 1,[11] as well as Prochaska and DiClemente's transtheoretical model of change that was developed for use in psychotherapy.[25] The cancer pain social processes theoretical framework identified behaviors and thought processes that were used by patients, family caregivers, and nurses in daily pain management in the home. These included pain goals, efficacy, perception, physical-emotional distance, communication, and agreement.[11] Social processes underpinned cancer pain management behaviors in complex ways. By viewing these processes in a context of multiple pain management collaborators (patients, caregivers, and nurses), clinicians and researchers can pinpoint areas of need. A lack of communication about personal and functional pain goals was evident between patients and caregivers, and patients and nurses in the participants of the grounded theory research study from which the framework was constructed.[11] In the study proposed here, we will specifically target setting of patient reported cancer pain goals by focused communication between a nurse and patient that uses motivational interviewing.

4.5 Motivational Interviewing to Set Patient-Reported Functional Pain Goals

MI is a cognitive behavioral approach that promotes coping by guiding patients to assess their circumstances and choose interventions specific to their needs and values. Working with patients to increase feelings of control is inherent to MI. MI has been used in both brief and extended clinical healthcare settings.[26] Two cancer pain studies have included MI as an element of a comprehensive intervention. Thomas et al. studied the effect of an MI-based telephone coaching intervention by a clinical nurse specialist as part of an RCT to help 318 patients manage their cancer-related pain.[27] Significant findings were increased function and improved mental and overall health in the intervention group, with no significant changes in pain intensity or attitudes over 12 weeks.[27] Coolbrandt et al. used MI as one component of an early overall symptom management intervention for 143 cancer patients beginning chemotherapy, randomized to intervention and control groups.[28] The interventions included use of MI and tailored nurse coaching in an initial inpatient session followed by a nurse phone session between two and four weeks later. They found that participants in the intervention group had significantly higher overall symptom self-efficacy scores at six weeks post-intervention than the control group (M 74, M 69, p.02 respectively).[28] To date, studies measuring the effect of MI on patient reported perceived control over cancer pain and pain self-efficacy have not been conducted. Nor have feasibility or patient acceptability of MI for cancer pain management been studied. However, feasibility studies have been conducted in other healthcare populations. For example, MI feasibility and fidelity were demonstrated in an RCT where trained community health workers delivered a brief culturally-tailored MI intervention to increase breast cancer screening rates for African American women visiting emergency departments.[29]

Applying MI techniques for patients with cancer pain approaches the complex relationships underlying self-efficacy and perception of pain intensity, along with functional capacity by acknowledging the complicated nature of psychosocial and environmental issues. For example, we used constructivist grounded theory methods to generate the hospice caring triad cancer pain social processes framework, from which we identified social

processes and their breakdowns in nursing pain management with patients and family caregivers.[11] Differences were reported in perception of pain control, communication about pain goals was lacking, and differences in physical-emotional distance occurred within groups of patients, caregivers, and nurses managing cancer pain at the end of life. Our theoretical framework (see Figure 1) provided an evidence-based outline of potential problem areas that researchers can use in developing interventions for improving pain outcomes when usual evidence-based practices do not seem to be effective in clinical contexts. The key problem identified in our study was the lack of communication with patients about any pain goals in developing plans for managing pain.[11]

5.0 Inclusion and Exclusion Criteria*

5.1 Screening Procedures:

The PI or another member of the research team will view the ambulatory palliative care consult schedule weekly to identify eligible patient participants. The PI will then contact the scheduled provider to inform that the patient is eligible and to request permission to approach the patient in clinic after the scheduled consultation visit.

5.2 Sample Inclusion Criteria:

- At least 18-years of age
- Has an appointment with DFCI ambulatory palliative care service for cancer-related pain
- Can speak English

5.3 Exclusion Criteria:

- Diagnosis of delirium or other cognitive impairment

5.4 Special populations:

- None

6.0 Study-Wide Number of Subjects*

- We anticipate an overall study sample of 54 participants.

7.0 Study Timelines*

7.1 Participant duration in study:

Each participant will be enrolled in the study for the time it takes to return for their four scheduled intervention sessions, as long as those visits end by the time data collection closes, at the end of study month 10 (August 2019). The exact duration for each participant will be dependent on their clinic schedules with which the MI study intervention sessions will be aligned, as well as how many of the four MI intervention sessions individual participants complete. An example of brief participation is a participant who completes the initial session and returns for a second and final session one week later. An example of full participation is a participant who completes the initial session and returns for a total of four sessions prior to the study ending. Please see the study schema for a graphic depiction of the study timeline.

7.2 Estimated study completion time:

We anticipate that this research study will be ongoing for one year. Recruitment will occur over nine months. Data collection will begin at the time of recruitment and end when the last participant recruited in that period has completed up to four intervention sessions. Data analysis will take approximately two months. Complete analysis and processing of results is anticipated to conclude twelve months after the first day of recruitment.

8.0 Study Endpoints*

8.1 Data collection instruments:

To measure the study endpoints outlined in the specific aims, we will use the following instruments:

Intervention Feasibility (Aim 1)	Rate of participants completing at least two MI intervention sessions; study spreadsheet
Participant Total Intervention Usage (Aim1)	Rate of completed interventions out of four possible; study spreadsheet
Patient Intervention Acceptability (Aim 1)	Patient Experience Questionnaire (investigator-developed)
Attitudinal Barriers (Aim 2)	Barriers Questionnaire II (Ward & Gunnarsdottir, 2002)
Pain Self-Efficacy (Aim 2)	Pain Self-Efficacy Questionnaire (Nicholas, 1989)
MI Patient Engagement in Goals-Setting (Aim 2)	Observed Engagement Table (investigator-developed)
MI Fidelity	Motivational Interviewing Skills in Health Care Encounters (Petrova et al., 2015)

8.2 Measures:

8.21 Intervention feasibility (Aim one): Feasibility and total intervention usage rates will be calculated by extracting number of visits per participant from the research study registration spreadsheet. Intervention feasibility will be assessed by calculating the proportion of enrolled participants completing at least one follow-up MI session (at least two sessions total). The proportion of patients completing at least one follow-up intervention session will be estimated along with an exact 90% confidence interval. The MI intervention will be considered feasible if a 60% follow-up completion rate can be reached. With 54 participants, at least 26 (41%, 90% CI 36-60%) need to complete a follow-up interview to ensure that the upper bound of the exact 90% confidence interval contains 60%. Feasibility will be met for all participants completing at least two MI intervention sessions. The total intervention usage rate for each participant will be described by the number of interventions sessions attended divided by the total possible number of interventions sessions reported as the sample mean; the usage rate will be described (mean/std, median/range)..

8.22 Participant intervention acceptability (Aim one): The Patient Experience Questionnaire (PEQ), developed by the investigator, will be used to summarize overall patient-reported acceptability in this study. Summary measures of median/range and mean/SD for total categorical PEQ scores, the time in weeks from the initial to follow-up intervention visit, and the number of completed intervention sessions will be reported.

8.23 Participant pain barriers (Aim two): Attitudinal barriers to pain management will be measured using the BQ-II which measures four attitudinal realms with 27 self-rated questions about pain beliefs. The BQ-II has been used in cancer pain studies with psychometrics demonstrating validity and reliability. For cancer patients, internal consistency of 0.89 (mean 1.52, SD 0.73) was reported and higher barriers were significantly correlated with increased age ($r=0.18$, $P=0.02$).[30] The total score for the BQ-II and PSEQ will be calculated at study entry and after the first follow-up visit and scores will be summarized (median/range, mean/SD). The paired difference in PSEQ and BQII will be estimated along with a 90% confidence interval. If additional sessions are completed, the scores for PSEQ and BQII will be plotted over time and trends will be explored with graphical methods. Spearman's correlation between the PSEQ and BQII will be estimated along with a 90% confidence interval at each measured time point.

8.24 Participant self-efficacy (Aim two): The study team will look at the correlation among the measures being explored, described herein: Pain self-efficacy will be measured using the PSEQ. In patients with a history of chronic pain and mean pain level rated at 6.2 out of 10, PSEQ demonstrated excellent internal consistency with an alpha of 0.92 and a test-retest reliability from baseline to three months of $r=0.73$, $P<0.001$.[31] The total score for the BQ-II and PSEQ will be calculated at study entry and after the first follow-up visit and scores will be summarized (median/range, mean/SD). The paired difference in PSEQ and BQII will be estimated along with a 90% confidence interval. If additional sessions are completed, the scores for PSEQ and BQII will be plotted over time and trends will be explored with graphical methods. Spearman's correlation between the PSEQ and BQII will be estimated along with a 90% confidence interval at each measured time point.

8.25 Participant engagement in goal-setting (Aim two): Observed Engagement will be evaluated using the instrument developed by the investigator for this study in which behaviors indicative of active goal setting will be tabulated by the PI or RA. Observed engagement will be summarized categorically, and salient quotes will be extracted into the OET to give voice to participant experiences in study results dissemination.

8.25.1 The study team will look at the correlation among the measures being explored, specifically, pain barriers (BQII) and self-efficacy (PSEQ). The paired difference in BQII and PSEQ scores from sessions one and four will be estimated, along with a 90% confidence interval. If additional sessions are completed, the scores for BQII and PSEQ will be plotted over time and trends will be explored with graphical methods. Spearman's correlation between BQII and PSEQ will be estimated along with a 90% confidence interval at each measured time point.

8.26 MI intervention fidelity: Fidelity to MI methods will be assessed on 33% of interviews using the MISHCE which was developed specifically to measure fidelity in brief healthcare encounters. MISCHE evaluates the degree to which the person providing the MI session follows five domains key to MI. The domains are: 1) MI philosophy, 2) health interviewing, 3) motivation, 4) MI principles, and 5) interpersonal process. Each domain has specific behaviors that are rated as 1) deficient, 2) developing, 3) accomplished, or 4) N/A. MISHCE demonstrated acceptable internal consistency (0.75, CI 95%), good inter-rater reliability (15 of 22 intraclass correlation coefficients were excellent, 5 were good, 1 was fair and 1 was poor), and good-to-excellent test-retest reliability.[32] Fidelity assessment will be conducted by the PI or RA.

9.0 Procedures Involved*

9.1 Study design:

This is a single-arm pilot study to assess feasibility and acceptability of a motivational interviewing intervention which will entail two-to-four intervention sessions per participant, participant completion of a battery of questionnaires specific to the intervention session, an investigator-led MI intervention at each session, and summary statistics (described below).

9.2 Study Procedures:

After written informed consent has been obtained and verbal consent confirmed participation in this study will involve between two and four intervention sessions.

9.21 Study Participation Compensation: Participants will be compensated with $25 gift cards at the first and last visits (anticipated to be visits 1 and 4). Pending receipt of additional funding for participant compensation, participants may also be compensated at visits 2 and 3, if these are in addition to the first and last visits, and if this funding is granted to the research study.

9.22 Intervention Sessions: Each intervention session will include a battery of questionnaires, an MI intervention, and the investigator completing a goal(s) summary for the participant to take away. Participants may opt to complete Intervention Sessions 2, 3, and 4 in person on the DFCI campus or via telephone (or a mix). Session-specific content is outlined below. Session-specific content outlined below.

Session 1:

Questionnaires:	Demographics survey* Pain location diagram (paper and pencil) BQ-II* PSEQ*
MI Intervention	Investigator-led discussion (described below)
Goals Summary	Completed by investigator
Gift Card ($25)	Disbursed

* Paper and pencil form or tablet computer per participant preference.

Sessions 2 & 3:

Questionnaires:	BQ-II* PSEQ*
MI Intervention	Investigator-led discussion (described below)
Goals Summary	Completed by investigator
Gift Card ($25)	None (Pending additional funding)

* Paper and pencil form or tablet computer per participant preference.

Session 4:

Questionnaires:	BQ-II* PSEQ* PEQ*
MI Intervention	Investigator-led discussion (described below)
Goals Summary	Completed by investigator
Gift Card ($25)	Disbursed

* Paper and pencil form or tablet computer per participant preference.

Motivational Interviewing Sessions:

Motivational Interviewing Intervention: An investigator-led discussion about the participant's pain experience which is focused on the participant reporting of functional pain goals (FPGs). The investigator will elicit questions and goals that participants will be encouraged to discuss with their palliative care providers.	Key elements of intervention: • Establish rapport • Open and closed questions • Reflecting • Gaging ambivalence • Permission to give information • Pain-related problems • Feelings related to pain meaning • Perceptions about what will happen with the pain • Desired pain management outcomes (FPGs) • Pain management interventions acceptable to participant

9.3 Data to be collected:

Source data will be collected in the battery of questionnaires described above. All source data questionnaires are included at the end of this protocol. These source data documents and records, except for the IRB-approved written informed consent document will be labeled with numeric identifiers only to protect participants confidentiality. All paper versions will be filed in a secure locked filing cabinet in the PI's office at the Cantor Center, accessible to research study team members. All digital data source records will be retained in REDCap (demographics, BQ-II, PSEQ, PEQ) or in study spreadsheets in the Cantor Center shared drive protected by Partners IS, or on the encrypted laptop computer of the PI.

9.4 Participant Registration:

Institutions will register eligible participants in the Clinical Trials Management System (CTMS) OnCore as required by DF/HCC SOP REGIST-101.

10.0 Data Banking*

10.1 Questionnaires

Survey data from the questionnaires, including demographics, BQ-II, PSEQ, and OET, and MI intervention session audio-recordings will be stored in the Cantor Center shared drive protected by Partners IS, or on the encrypted laptop computer of the PI for the IRB-required time frame.

10.2 Transcripts

De-identified transcripts from the MI intervention sessions will be banked by the Cantor Center for future research purposes such as qualitative data analysis. These files will be stored securely in the Cantor Center shared drive protected by Partners IS.

10.3 Accessing

Researchers, including investigators from collaborating institutions, can request de-identified data from this study for new research. Data may also be shared with outside non-profit academic investigators. Researchers may request access by making a request in writing to the PI and submitting appropriate IRB approval processes.

11.0 Data Management* and Confidentiality

11.1 Analysis:

Statistical data analysis will be conducted by the research team statistician. Testing procedures were outlined in section 8.2, above.

MI intervention fidelity testing will be conducted on 33% of the audio-recorded sessions, by the PI or RA, as described above. The number of sessions to be reviewed assuming a total sample of 54 participants, seen for two interventions at least (108 x .33) will be 37, and will be conducted on a bi-weekly schedule.

11.2 Training:

The study will be reviewed and approved by the Dana Farber Cancer Institute IRB. The PI and study staff will have completed the Collaborative Institutional Training Initiative Human Subjects Training Program and all other training required by DFCI. In addition, the PI and study staff will also practice the informed consent process with the RA(s). Before beginning the research study, the PI will obtain written and dated approval from the IRB for the study protocol, written informed consent form, EMR abstraction forms, subject recruitment procedures, and any written information to be provided to subjects. Any future protocol amendments or consent form updates must also be approved by the IRB.

The PI will provide education to the research team members about participant eligibility identification, recruitment, and consenting training, participant entry into the study data spreadsheet, and use of the MISCHE for fidelity evaluation.

12.0 Withdrawal of Subjects*

12.1 Participant withdrawal:

Unless the patient's clinician states that the study is no longer in their best interest, there are no anticipated circumstances in which a patient will be withdrawn from the research without their consent. If a patient requests to be removed from the research study, we will document their reason for dropping out of the study and update their status in OnCore.

13.0 Potential Risks to Subjects*

There are no physical risks to taking part in this research. The risks related to this study include a risk for loss of privacy and also the risk that some items on the questionnaires might cause feelings of unease or distress. If talking about their cancer pain experience is upsetting, the researcher will arrange a visit with a medical social worker, or provider in the clinic. There is a possibility that participants could experience physical pain from their cancer during the interventions sessions. The PI is a board-certified hospice and palliative care nurse with

experience assessing and providing nursing interventions for discomforting symptoms. She will intermittently ask participants if they are experiencing discomforting pain. If so, they will be prompted to follow their medication orders and asked if they would like to reschedule the intervention appointment. The nature of risks to subjects is low, and the anticipated risks are likely to be reversible within minutes-to-hours.

14.0 Potential Benefits to Subjects*

Participants in this research study may experience improved pain control, less discomfort from pain, or an enhanced sense of empowerment about managing their pain. Participants may set functional pain goals which could help them discuss their pain management plans with providers and family caregivers.

15.0 Vulnerable Populations*

- No vulnerable populations will be recruited.

16.0 Sharing of Results with Subjects*

Sharing overall study results with participants is not planned, however the nature of MI discussions involves recapping what has been said to clarify key points in the talking interventions. Participants will be provided with the opportunity to learn about their individual barriers and self-efficacy scores. We plan to disseminate results of this study in a peer-reviewed journal and at a professional conference.

17.0 Setting

Participant recruitment will take place in the ambulatory clinics where eligible patients are being seen for their scheduled palliative care consultations at DFCI. In-person study intervention visits will take place in private areas in the ambulatory clinics, consultation rooms, or meeting rooms on the DFCI campus. For participants who opt to have sessions 2, 3, or 4 via telephone, questionnaires will be given in person at session 1 or mailed to them in an unmarked envelope. The investigator will read the questionnaire aloud over the telephone as the participant reads their copy and the investigator will write their responses on the paper forms to be recorded in the Redcap database. Participant permission to audio record the intervention sessions will be obtained prior to beginning the motivational interviewing intervention each time. The intervention session(s) will be recorded via the telephone using the same recording equipment that is utilized for in-person intervention session interviews.

18.0 Resources Available

18.1 Research team qualifications:

The study overall PI, Dr. Olga Ehrlich, is a post-doctoral fellow at the Phyllis F. Cantor Center for Research in Nursing and Patient Care whose full-time role is dedicated to research training. Dr. Ehrlich has conducted two prior research studies with patients experiencing pain from cancer, both in the home hospice setting. In those studies, she collaborated with healthcare agency administrators and clinicians to identify and recruit patients, nurses, and family caregivers, administered demographics surveys, and conducted extended audio-recorded private interviews with all participants to collect data. She has conducted analysis of qualitative data resulting in publication and presentation at professional conferences. As an experienced and board-certified hospice and palliative care clinician, with training in MI, she is qualified to conduct the MI intervention which will be tested for feasibility in this study, with a sample of participants experiencing pain from cancer. Dr. Ehrlich has the clinical knowledge and experience to assess and intervene if study participants experience physical or emotional discomfort during study interventions sessions. Additionally, she has completed applied biostatistics training through the Harvard Catalyst program and is collaborating with Cantor Center biostatistician, Traci Blonquist, MS, for statistical testing in this study. Dr. Donna Berry, nurse scientist in the Cantor Center, and Dr. Ehrlich's mentor, is Co-Investigator for this study.

18.2 Facilities support:

Study staff will conduct administrative and operations procedures at the Cantor Center. Resources available through the Center include study managers, research assistants, secure private offices, computers and software, secure locked storage for print data, and encrypted digital storage for study computer files, including REDCap. Cantor Center research staff have practical and ethical knowledge and training in the DFCI conduct surrounding research.

18.3 Capacity to recruit study sample:

The study sample will include patients at least 18-years old with any type of cancer who have been referred to the Dana-Farber Cancer Institute adult ambulatory palliative care service for cancer-related pain. Approximately 63 new patients are seen by the palliative care service per month, and it is estimated that 37 will require follow-up visits within the study-required time period of 1-4 weeks for a return visit. Assuming a 50% consent rate, it is estimated that approximately 18 participants per month will be accrued over a three-month recruitment period for a total sample size of 54 participants, if all eligible participants can be approached on the first scheduled day. To accommodate the likelihood of cancelled or rescheduled appointments, or participants with appointments scheduled for the same times, we will extend our recruitment period for up to nine months. With 54 participants, the exact 90% confidence interval for the proportion of participants completing at least one follow-up MI session will be not wider than +/- 11.9%.

19.0 Prior Approvals

- The PI has obtained approval intent to collaborate from Dr. Douglas Brandoff, and Daniel Gorman, NP-C, of the DFCI Palliative Care Service.
- The PI has applied for, and has received, external funding for this research study.

20.0 Recruitment Methods

20.1 Sample:

Patients who have been referred to the DFCI Palliative Care Service ambulatory program for a pain consultation will be considered for participation in the study.

20.2 Eligibility determination:

The PI or RA will use the eligibility check list which is part of the written informed consent document to determine eligibility when scanning the EPIC schedule for potential participants

20.3 Recruitment methods:

During the 3-month long recruitment and enrollment period, the PI and a RA will scan the Palliative Care Service ambulatory clinic visit schedule in EPIC, at least weekly to identify study-eligible patients. The Palliative Care Service provider who has been scheduled to see the eligible patient(s) will be contacted by the PI or RA via Partners secure email to inform them of patient eligibility and to discuss approaching patients for the study. Unless the provider(s) indicate that approaching an eligible patient would be inappropriate, the PI or RA will approach the eligible patient in the clinic site after their scheduled visit to describe the study and obtain informed consent, or to schedule another time to do so. To facilitate recruitment, Palliative Care team providers will be prompted to introduce the study to patients when possible. A brief introduction script will be included on the Clinician Prompt Sheet (attached) that a study team member will fill out for each approved participant. This sheet will be attached to the regular visit front sheet by clinical support employees the day prior to each planned approach.

21.0 Local Number of Subjects

21.1 Total sample

- We anticipate a total sample size of 54 participants.

21.2 Sample size calculations:

Assuming a 50% consent rate of the 63 patients seen by the palliative care service per month, it is estimated that approximately 18 participants per month will be accrued over a three-month recruitment period for a total sample size of 54 participants. With 54 participants, the exact 90% confidence interval for the proportion of participants completing at least one follow-up MI session will be not wider than +/- 11.9%.

22.0 Provisions to Protect the Privacy Interests of Subjects

22.1 Steps to protect participant privacy:

To minimize risks to privacy, all written study materials will be labelled with participant ID numbers instead of patient names. Only IRB-approved individuals will have access to the reference list. Data collection forms will be stored in a locked cabinet at the Cantor Center and will be de-identified prior to manual data entry into an Excel spreadsheet located on the Cantor Center Shared Drive. Questionnaire data will be collected in the study REDCap account, monitored by Partners IS. REDCap data will be de-identified and transferred for data analysis into Excel study data spread sheets. The research team is permitted to access the patients' EHR to obtain information about their clinicians' documentation of pain assessment and management (e.g., treatments prescribed). MI intervention sessions audio-recordings will be scrubbed of any identifying information (e.g. person's names, place names, institutions) by the PI or RA prior to audio-recordings being sent for transcription. Original audio-recordings will be maintained on the encrypted computer of the PI and/or in the Cantor Center Shared Drive for the time specified by the IRB.

22.2 Steps to increase sense of ease:

At the start of each MI intervention session, participants will be instructed that they do not have to answer questions which make them uncomfortable and they need not explain why they choose not to answer. They will also be informed that should they feel a sense of unease related to intrusiveness of questions, the PI is willing to discuss these feelings with them and make a referral to another appropriate professional, or to the IRB contact.

22.3 Identifying potential participants

The PI or RA will have access to the EHRs of potential patients through EPIC and will use the scheduling function to identify potentially eligible patients referred to Palliative Care.

23.0 Economic Burden to Subjects

Participation in this study will not involve added economic burden. There are no costs for study participation.

24.0 Consent Process

24.1 Written and verbal:

Written and ongoing verbal informed consent will be obtained. Written informed consent will be obtained in a private space at the DFCI clinic where eligible patients are being seen by their provider. To obtain written informed consent, the PI or RA will explain what participation in the study entails (number of visits and completion of questionnaires, MI intervention sessions), possible risks and benefits of participation, anticipated time participation will last, privacy protections to be undertaken, as well as the option to not participate, per the

approved DFCI OHRS written informed consent document (draft attached). The person obtaining consent will ask if there are questions and will answer any questions. The eligible patient will then be asked if they would like to participate, and if so will sign the IRB-approved consent document, witnessed and signed by the consenter. If eligible patients would like time to consider participation and are not ready to sign, they will be asked how they would like to follow-up. They may provide contact information and request follow-up contact from the study team, or they may request contact information for the PI and follow-up as they wish.

When the investigator meets with enrolled study participants for their first intervention session, she will inform them of a new option, approved by the IRB since they provided written consent. This option is for participants to complete intervention sessions 2, 3, and 4 via the phone in person or a mix of these. Each participant will be asked to state their preferences for in-person or telephone interventions. These preferences, reported verbally, will be recorded in the study participant enrollment log.

24.2 Waiting period:

There will not be a required waiting period between obtaining written consent and participants beginning the first study intervention session. However, participants who have given written consent will be informed that they may start the first study session at their next scheduled visit time, or another time that is convenient for them to visit DFCI.

24.3 Ongoing:

Verbal consent will be obtained by the PI at the beginning of each session and any time during the interventions sessions that participants appear uncomfortable or express distress. This verbal consent will involve asking a question like, “Are you comfortable continuing your participation in this study?”

24.4 SOP

This study will follow “SOP: Informed Consent Process (CON-100).”

25.0 Process to Document Consent in Writing

The PI or RA will follow “SOP: Informed Consent Process (CON-100)” when creating the informed consent document and using it to obtain written consent. The written consent document is attached at the end of this protocol (not yet approved by IRB).

26.0 References

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27.0 Appendices:

Study Documents

A. Electronic Health Record Abstraction Form
B. Demographic Questionnaire
C. Pain Self-Efficacy Questionnaire (PSEQ)
D. Barriers Questionnaire II (BQ-II)
E. Patient Experience Questionnaire (PEQ)
F. Observed Engagement Table
G. Motivational Interviewing Study Goal Summary
H. MISHCE and instructions

28.0 Appendix A: Eligible Participant Extraction Form

Electronic Health Record Abstraction Form – Potential Eligible Patients (for use with EPIC clinical schedule and EHR)

Clinic Appointment Date/Time (eg-4/2/18 15:45)	Provider: Last/First (eg-Carr, F)	Patient: Last/First (eg-Garcia, E)	MRN	Previous pain referral (eg-yes/no)

29.0 Appendix B: Demographic Questionnaire

Demographic Questionnaire

Age	
Gender identity	Female Male Other
Race	African American Asian American Native American Pacific Islander Asian African Caucasian/White Other:
Ethnicity	Hispanic Non-Hispanic
Cancer type (for example, colon.)	(list all)
Number of visits for pain treatment since your diagnosis (Your best estimate)	(fill in number)
Which types of clinicians provided pain treatment (for example: primary care MD, palliative care NP, oncologist, etc.)	(list all)
Is a caregiver involved in your pain management?	Yes No

Please mark any area(s) on your body where you have had pain related to your cancer in the past 24 hours.
[INSERT GRAPHIC OF BODY HERE:]

30.0 Appendix C: Pain Self-Efficacy Questionnaire

Pain Self-Efficacy Questionnaire (M. K. Nicholas, 1989)

Pain Self Efficacy Questionnaire
(PSEQ)

Date.....

Managing your pain

Please rate **how confident** you are that **you can do** the following things at present, **despite the pain**. To answer, **circle** *one* of the numbers on the scale under each item, where 0 = "Not at all confident" and 6 = "Completely confident".

For example:

Not at all confident						Completely confident
0	1	2	(3)	4	5	6

Remember, this questionnaire is not asking whether or not you have been doing these things, but rather **how confident you are that you can do them** at present, **despite the pain.**

	Not at all confident						Completely confident
I can enjoy things, despite the pain.	0	1	2	3	4	5	6
I can do most of the household chores (eg. tidying-up, washing dishes, etc.) despite the pain.	0	1	2	3	4	5	6
I can socialise with my friends or family members as often as I used to do, despite the pain.	0	1	2	3	4	5	6
I can cope with my pain in most situations.	0	1	2	3	4	5	6
I can do some form of work, despite the pain ("work" includes housework, paid and unpaid work).	0	1	2	3	4	5	6
I can still do many of the things I enjoy doing, such as hobbies or leisure activities, despite the pain.	0	1	2	3	4	5	6
I can cope with my pain without medication.	0	1	2	3	4	5	6
I can still accomplish most of my goals in life, despite the pain.	0	1	2	3	4	5	6
I can live a normal lifestyle, despite the pain.	0	1	2	3	4	5	6
I can gradually become more active, despite the pain.	0	1	2	3	4	5	6

31.0 Appendix D: Barriers Questionnaire II

Barriers Questionnaire II (S. E. Ward & S. Gunnarsdottir, 2002. Permissions follow instrument).

We are interested in learning about your attitudes toward treatment of pain. We want to know what you think. Some of the questions may seem similar to other ones, but please answer all of the questions. For each of the items below, please circle the number (0, 1, 2, 3, 4, or 5) that comes closest to how much you agree with that item.

1) Cancer pain can be relieved.

0	1	2	3	4	5
Do not agree at all					Agree very much

2) There is a danger of becoming addicted to pain medicine.

0	1	2	3	4	5
Do not agree at all					Agree very much

3) Drowsiness from pain medicine is difficult to control.

0	1	2	3	4	5
Do not agree at all					Agree very much

4) Pain medicine weakens the immune system.

0	1	2	3	4	5
Do not agree at all					Agree very much

5) Confusion from pain medicine can not be controlled.

0	1	2	3	4	5
Do not agree at all					Agree very much

6) When you use pain medicine your body becomes used to its effects and pretty soon it won't work any more.

0 1 2 3 4 5
Do not agree at all Agree very much

7) Using pain medicine blocks your ability to know if you have any new pain.

0 1 2 3 4 5
Do not agree at all Agree very much

8) Pain medicine can effectively control cancer pain.

0 1 2 3 4 5
Do not agree at all Agree very much

9) Many people with cancer get addicted to pain medicine.

0 1 2 3 4 5
Do not agree at all Agree very much

10) Nausea from pain medicine can not be relieved.

0 1 2 3 4 5
Do not agree at all Agree very much

11) It is important to be strong by not talking about pain.

0 1 2 3 4 5
Do not agree at all Agree very much

12) It is important for the doctor to focus on curing illness, and not waste time controlling pain.

0 1 2 3 4 5
Do not agree at all Agree very much

13) Using pain medicine can harm your immune system.

0 1 2 3 4 5
Do not agree at all Agree very much

14) Pain medicine makes you say or do embarrassing things.

0 1 2 3 4 5
Do not agree at all Agree very much

15) If you take pain medicine when you have some pain, then it might not work as well if the pain becomes worse.

0 1 2 3 4 5
Do not agree at all Agree very much

16) Pain medicine can keep you from knowing what's going on in your body.

0 1 2 3 4 5
Do not agree at all Agree very much

17) Constipation from pain medicine can not be relieved.

0 1 2 3 4 5
Do not agree at all Agree very much

18) If doctors have to deal with pain they won't concentrate on curing the disease.

0 1 2 3 4 5
Do not agree at all Agree very much

19) Pain medicine can hurt your immune system.

0 1 2 3 4 5
Do not agree at all Agree very much

20) It is easier to put up with pain than with the side effects that come from pain medicine.

0 1 2 3 4 5
Do not agree at all Agree very much

21) If you use pain medicine now, it won't work as well if you need it later.

Do not agree at all Agree very much

22) Pain medicine can mask changes in your health.

0	1	2	3	4	5
Do not agree at all					Agree very much

23) Pain medicine is very addictive.

0	1	2	3	4	5
Do not agree at all					Agree very much

24) Medicine can relieve cancer pain.

0	1	2	3	4	5
Do not agree at all					Agree very much

25) Doctors might find it annoying to be told about pain.

0	1	2	3	4	5
Do not agree at all					Agree very much

26) Reports of pain could distract a doctor from curing the cancer.

0	1	2	3	4	5
Do not agree at all					Agree very much

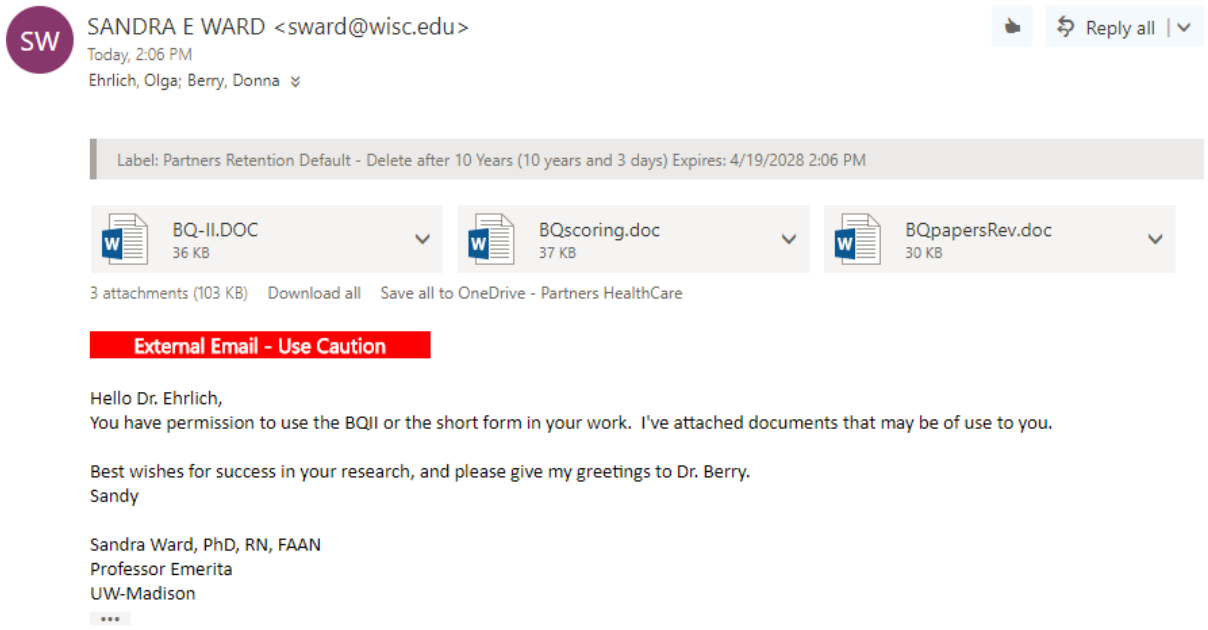
27) If I talk about pain, people will think I'm a complainer.

0	1	2	3	4	5
Do not agree at all					Agree very much

Scoring the Barriers Questionnaire-II

1. Items 1,8 and 24 (Fatalism) are reverse scored before analysis
2. The mean scores on the total scale (27-items) and subscales is used for analysis.

Subscale	**Items**	#
Physiological Effects		
	Drowsiness from pain medicine is difficult to control.	3
	Confusion from pain medicine can not be controlled.	5
	When you use pain medicine your body becomes used to its effects and pretty soon it won't work any more	6
	Using pain medicine blocks your ability to know if you have any new pain.	7
	Nausea from pain medicine can not be relieved	10
	Pain medicine makes you say or do embarrassing things	14
	If you take pain medicine when you have some pain, then it might not work as well if the pain becomes worse	15
	Pain medicine can keep you from knowing what's going on in your body	16
	Constipation from pain medicine can not be relieved.	17
	It is easier to put up with pain than with the side effects that come from pain medicine	20
	If you use pain medicine now, it won't work as well if you need it later	21
	Pain medicine can mask changes in your health	22
Fatalism		
	Cancer pain can be relieved.	1
	Pain medicine can effectively control cancer pain	8
	Medicine can relieve cancer pain	24
Communication		
	It is important to be strong by not talking about pain	11
	It is important for the doctor to focus on curing illness, and not waste time controlling pain.	12
	If doctors have to deal with pain they won't concentrate on curing the disease	18
	Doctors might find it annoying to be told about pain	25
	Reports of pain could distract a doctor from curing the cancer.	26
	If I talk about pain, people will think I'm a complainer.	27
Harmful Effects		
	There is a danger of becoming addicted to pain medicine	2
	Pain medicine weakens the immune system	4
	Many people with cancer get addicted to pain medicine	9
	Using pain medicine can harm your immune system	13
	Pain medicine can hurt your immune system	19
	Pain medicine is very addictive	23



SW

SANDRA E WARD <sward@wisc.edu>

Today, 2:06 PM

Ehrlich, Olga; Berry, Donna

Reply all

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BQ-II.DOC 36 KB

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External Email - Use Caution

Hello Dr. Ehrlich,
You have permission to use the BQII or the short form in your work. I've attached documents that may be of use to you.

Best wishes for success in your research, and please give my greetings to Dr. Berry.
Sandy

Sandra Ward, PhD, RN, FAAN
Professor Emerita
UW-Madison

32.0 Appendix E: Patient Experience Questionnaire

Patient Experience Questionnaire

Study ID # (to be filled out by study coordinator):

Instructions: For questions 1-6, please circle the answer that best describes your experience.

1) Were these sessions talking about pain helpful for you?	YES	NO	NOT SURE
2) Were these sessions worth your time?	YES	NO	NOT SURE
3) Would you recommend this type of pain session to others with pain from cancer?	YES	NO	NOT SURE
4) Were you able to set a goal of something you hoped to achieve by having control of the pain?	YES	NO	NOT SURE
5) Did you discuss your participation in these sessions, or parts of what we talked about, with your healthcare team?	YES	NO	NOT SURE
6) Would you suggest also including caregivers these sessions?	YES	NO	NOT SURE

For question 7, please write as much or as little as you would like to share.

7) Please let the research team know any other thoughts about your experiences with these sessions:

33.0 Appendix F: Observed Engagement Table

Observed Engagement Table
(For research team use, data collection)

Category	*Count*	*Quote*
A) Pain as obstacle		*Example: "I wish I could drive to pick my son up from school***."**
B) What helped pain before		*Example: "I have used a heating pad on my belly with some relief."*
C) Life with controlled pain		*Example: "I would really like to visit my sister in Florida next month."*
D) Suggestions to control pain		*Example: "Perhaps I should take my oxycodone IR every four hours instead of every eight."*
D) Patient suggestions used		*Example: "Since I saw you last time I have been taking my oxycodone IR more often, not exactly every four hours, but some days that much."*
E) Patient help-seeking		*Example: "I really need someone to explain when I can take the as-needed medication versus the long-acting to my husband."*

34.0 Appendix G: Intervention Goal Summary

Motivational Interviewing Study Goal Summary – For Participant Use

At the session on _____(date), the following functional pain goal(s) was(were) identified:

1.

2.

3.

4.

35.0 Appendix H: MISHCE

"This instrument has been used with permission by the developer of the Motivational Interviewing Skills for Health Care Encounters – MISHCE, Tatjana Petrova, PhD, Specialist in Clinical Pharmacy, Associate Professor, Department of Pharmacy Practice at Chicago State University. The MISHCE was developed in a project entitled, "Designing an Instrument for Measuring Motivational Interviewing Skills Acquisition in Healthcare Professional Trainees" at Auburn University."

[Note: Please be advised that there has generally not been a fee for single use of the entire MISHCE when undertaken as part of a fellowship, graduate, or undergraduate student project or by researchers based at academic institutions or community non-profit organizations who are funded by federal or foundation grants. If there are any plans to make use of the MISHCE as part of a non-grant funded health care organization or provider Motivational Interviewing project, or if there are plans to do ongoing assessments as part of a larger project or make derivative uses of the tool, or if the organization is a for-profit entity, please contact the developer].

Motivational Interviewing Skills for Health Care Encounters – MISHCE

Trainee:	Evaluator:	Date:

Rating

0=Deficient (MI-adherent skill not evident in interaction, although skill was necessary for facilitating the interaction)
1=Developing (MI-adherent skill partially present, or skill is present on a basic/simplistic level)
2=Accomplished (MI-adherent skill is well developed and sophisticated)
N/A= Not applicable (MI-adherent skill not evident and not necessary for facilitating the interaction)

Specific Guidelines:

- For each skill choose only one of the four options from the scale above.
- Use N/A (Not applicable) when, based on your evaluation, a certain skill was not evident in the interaction and it was not necessary for the trainee to use that skill to further facilitate the interviewing process.
- Ratings should capture only the health care provider behavior during the interaction.
- The skills in the domains MI Philosophy, Health Interviewing and Motivation are evaluated on a three-point rating scale. The three rating points are Deficient, Developing and Accomplished. Evaluate each skill of these three domains as an episode that occurs during the interaction rather than a certain behavior. Focus on the quality of the episode as a whole. Mark "X" in one of the four boxes to the right of the item (skill), depending on whether you have evaluated the skill as "Deficient", "Developing", "Accomplished" or "N/A".
- The skills in the domains MI Principles and Interpersonal Process are evaluated on the same three-point rating scale: Deficient, Developing, or Accomplished. Evaluate each skill of these domains based on behavioral occurrences demonstrated by the trainee. When noticing that the trainee has demonstrated the behavior, mark "X" in one of the four boxes to the right of the item (skill), depending on whether you have evaluated the behavioral occurrence as "Deficient", "Developing", "Accomplished" or "N/A".

MI PHILOSOPHY	**Deficient**	**Developing**	**Accomplished**	**N/A**
Exhibits the 'Spirit of MI'				
HEALTH INTERVIEWING	**Deficient**	**Developing**	**Accomplished**	**N/A**
Elicits / addresses patient's understanding about the illness and / or treatment				
Elicits / addresses patient's awareness of susceptibility / risk of uncontrolled illness / condition				
Elicits / addresses patient's desired health outcomes / goals				
MOTIVATION	**Deficient**	**Developing**	**Accomplished**	**N/A**
Elicits / addresses patient's motivators and barriers for behavioral change				
Reflects and affirms change talk				
MI PRINCIPLES	**Deficient**	**Developing**	**Accomplished**	**N/A**
Expresses empathy				
Supports self-efficacy				
Rolls with resistance				
Develops discrepancy				
INTERPERSONAL PROCESS	**Deficient**	**Developing**	**Accomplished**	**N/A**
Resists the righting reflex				
Uses reflective listening				
Uses open-ended questions				
Uses agenda setting				
Moves smoothly through the interaction				